

# **EPA Registration Jacket 35484-6**

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 490508		Registration #: 35484-A	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: metalaxyl			
Fee Category: R333		PRIA Decision Time Frame: 10 months	
Submitted by: Hope Johnson		Branch: OCSPP/OPP/RD	Date: 03/12/2015
Company: Industrias Quimicas Del Valles, SA (IQV, SA) c/o Landis International, Inc.			
Original PRIA Due Date: 03/16/2015		Proposed New PRIA Due Date: 05/14/2015	
Previous Negotiated Due Dates:			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 04/01/2015	
Negotiated Due Date Reason:			
Additional Data Required	<input checked="" type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	<input type="checkbox"/> Toxicology
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	<input type="checkbox"/> Other
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input checked="" type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
The Registrant was notified 3/11 by phone and again on 3/12 by phone and email of the deficiencies of their product chemistry data. They believe they can correct the data in a timely manner and agreed to a 60 day renegotiation by email on 3/12.			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? Add comments on page 2			
Rationale for Proposed Due Date: 60 days- Registrant can submit quickly, remaining time for review			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 03/12/2015

Decision #:	Registration #:	Petition #:

**Issue(s) (describe in detail):**

The product chemistry review was received on 3/11/15 by the PM team. It identified deficiencies related to discussion of formation of impurities (clarification needed between 2 MRIDs submitted), stability of metal and metal ions (data was not submitted), and reduction (data for oxidation/reduction did not include reduction information). When notified, the Registrant stated it could clarify the impurity question quickly and would submit waivers for the stability of metal and metal ions and reduction. Once this data/waivers are submitted, the PM team will request Product Chemistry to review expeditiously.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-15071113632-HJ

SUBMITTED on 03/12/2015 at 03:20:52 PM by CN=Hope Johnson/OU=DC/O=USEPA/C=US

APPROVED on 03/12/2015 at 03:27:55 PM by CN=Cynthia Giles-Parker/OU=DC/O=USEPA/C=US

APPROVED on 03/12/2015 at 03:31:52 PM by CN=George Herndon/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 03/12/2015 at 03:44:43 PM by CN=Marty Monell/OU=DC/O=USEPA/C=US

## Johnson, Hope

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**From:** Crystal Layton <clayton@landisintl.com>  
**Sent:** Thursday, March 12, 2015 3:08 PM  
**To:** Johnson, Hope  
**Cc:** Howard, Marcel; Giles-Parker, Cynthia  
**Subject:** RE: 35484-A- PC issues and renegotiation need

Dear Hope,

We accept the 60 day renegotiation from March 16, 2015 to May 14, 2015 for EPA File Symbol Number 35484-A; Decision Number 490508.

We plan to address the deficiencies and submit a response next week. We appreciate your efforts in having the response reviewed in a timely manner.

Thank you,

Crystal

Crystal Layton, Regulatory Product Manager  
Landis International, Inc. · 3185 Madison Highway · Valdosta, GA 31601 · USA  
Phone: (229) 247-6472 · Cell: (229) 548-2806 · Fax: (229) 242-1562  
email: [clayton@landisintl.com](mailto:clayton@landisintl.com) · skype: crystal.layton

**From:** Johnson, Hope [mailto:Johnson.Hope@epa.gov]  
**Sent:** Thursday, March 12, 2015 11:24 AM  
**To:** Crystal Layton  
**Cc:** Howard, Marcel; Giles-Parker, Cynthia  
**Subject:** FW: 35484-A- PC issues and renegotiation need

Good morning,

Per our conversation, the current product chemistry issues are as follows:

- 1) 830.1670 (Discussion of the Formation of Impurities)- identity of Impurity 2 (identified by phone to you) needs clarification between MRID -01 and -02
- 2) 830.6313 (stability to normal and elevated temperatures, metals and metal ions)- No data was submitted regarding stability to metals and metal ions
- 3) 830.6314 (oxidation/reduction)- reduction potential was not evaluated. Product should be tested for compatibility with water, monoammonium phosphate or carbon dioxide, powdered zinc or iron, and potassium permanganate.

Due to the above data issues, a renegotiation of 60 days is needed to allow submission of the outstanding data and review. We will make every effort to review this in a timely fashion once submitted.

Please respond citing the following, and accepting the 60 day renegotiation from March 16, 2015 to May 14, 2015. EPA File Symbol Number 35484-A; Decision Number 490508. If you could send this response today I would appreciate it.

Thank you,

Hope

Hope A. Johnson  
Product Manager 21  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division  
Fungicide Branch  
Phone: 703-305-5410  
Mail Code 7505P

**From:** Johnson, Hope  
**Sent:** Thursday, March 12, 2015 6:26 AM  
**To:** 'Crystal Layton'  
**Cc:** Howard, Marcel  
**Subject:** 35484-A- please contact me this morning

Good morning,

I am hopeful that Marcel was able to speak with you yesterday regarding this action. Product Chemistry has notified us of deficiencies so we cannot move forward with this application until those are resolved. Therefore, we need to renegotiate this action. Please call me at your earliest convenience today.

Thank you,

Hope A. Johnson  
Product Manager 21  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division  
Fungicide Branch  
Phone: 703-305-5410  
Mail Code 7505P

# PROCESSING REQUEST

Reg # 35484-6

Decision # 490508

Description: New Technical for Metakay

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

☒ Dated: 4/7/2015

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Marcel Howard

Division: Registration Division

Phone: (703)305-6784

Date: 4/8/2015



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

EPA Reg. Number:

35484-6

Date of Issuance:

4/7/15

Term of Issuance:

Unconditional

Name of Pesticide Product:

Metalaxyl Technical

Name and Address of Registrant (include ZIP Code):

Industrias Quimicas del Valles, S.A. (IQV, SA)  
Avenida Rafael Casanova 81 08100  
Mollet del Valles (Barcelona-Spain)

c/o:

Landis International, Inc.  
P.O. Box 5126  
Valdosta, GA 31603-5126

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Hope Johnson, Product Manager 21  
Fungicide Branch, Registration Division (7505P)

Date:

4/7/15



2. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 35484-6."
  - Add an appropriate EPA Establishment Number
3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04-14-2014

If you have any questions, please contact Marcel Howard by phone at (703)305-6784, or via email at [howard.marcel@epa.gov](mailto:howard.marcel@epa.gov).

Enclosures: Product Chemistry Reviews; DP426478 and DP421173; dated 03/31/2015 and 03/11/2015  
Toxicity Review; DP420724; dated 06/06/2014  
Stamped "Accepted" product label

**ACCEPTED**

04/07/2015

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended for the  
pesticide registered under  
EPA Reg. No. 35484-6

**Metalaxyl Technical  
For Manufacturing Use Only**

Active Ingredient:

Metalaxyl\* [Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-DL-alaninate]:.....98.60%

Other Ingredients:.....1.40%

Total:.....100.00%

\*CAS No.: 57837-19-1

**KEEP OUT OF REACH OF CHILDREN****WARNING**

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> <li>• Take off contaminated clothing</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
IF INHALED	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	
<p><b>HOT LINE NUMBER:</b></p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on (product, use, etc.), call the National Pesticides Information Center (NPIC) at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week (NPIC Web site: <a href="http://www.npic.orst.edu">www.npic.orst.edu</a> ).</p> <p>During other times, call the poison control center 1-800-222-1222.</p>	
See side/back panel for additional precautionary statements.	

EPA Registration No. 35484-X

EPA Establishment No. XXXXXX-XXX-XXX

Net Contents: 55.11 pounds (25 kilograms)

**Manufactured for:**

INDUSTRIAS QUIMICAS DEL VALLES, S.A. (IQV, SA)	
Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain)	PO BOX 5126 VALDOSTA, GA 31603-5126 USA

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

**WARNING**

Causes substantial but temporary eye irritation. Harmful if swallowed or absorbed through the skin. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE): Wear long-sleeved shirt and long pants, socks, shoes, protective eyewear, and gloves made out of waterproof materials (solvent category A).

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is for use only in the formulation of fungicides. This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the US EPA data submission requirements regarding the support of such use(s).

**FOR MANUFACTURING USE ONLY AS A FUNGICIDE FOR THE FOLLOWING USES:**

**1. Seed Treatment Uses:**

Carrots  
Cotton  
Cucumbers  
Forage Legumes (Alfalfa, Clover, Lespedeza, Beans for Forage, Soybeans for Forage, Soybean Hay, Peanuts for Forage, Peanut Hay, Peas for Forage, Pea Vine Hay, Cowpeas for Forage, Cowpea Hay, Trefoil, Vetch, and Velvet Beans for Forage)  
Garden Beets  
Grain Crops (Wheat, Barley, Rye, Oats, Millet, Milo, Field Corn, Sweet Corn, Popcorn, Buckwheat, and Triticale)  
Peanuts  
Peas  
Rice  
Soybeans  
Sorghum  
Spinach  
Sugar Beets  
Sunflowers

Seed and Pod Vegetables (Black-Eyed Peas, Chickpeas, Garbanzos, Cowpeas, Dill, Edible Soybeans, Field Beans, Field Peas, Garden Peas, Green Beans, Kidney Beans, Lima Beans, Lupines, Navy Beans, Okra, Peas, Pole Beans, Snap Beans, String Beans, Wax Beans, and Lentils) Grasses (Turf and Forage)

2. Uses for which the US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with US EPA requirements.

#### **STORAGE AND DISPOSAL**

DO NOT contaminate water, food, or feed by storage or disposal.

**STORAGE:** Always use original container to store pesticides in a cool, dry secured warehouse or storage building. DO NOT store near food and feed. Containers should be opened in well-ventilated areas.

Keep container tightly sealed when not in use.

**PESTICIDE DISPOSAL:** Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

#### **CONTAINER HANDLING:**

**Plastic or Paper Bags:** Nonrefillable container. DO NOT reuse or refill this container.

Completely empty bag into manufacturing equipment. Offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### **CONDITIONS OF SALE AND LIMITED WARRANTY**

The Directions For Use of this product reflects the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. To the extent permitted by law, all such risks shall be assumed by the Buyer.

IQV, S.A. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use, subject to the inherent risks, referred to above.

IQV, S.A. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT PERMITTED BY LAW, IQV, S.A. AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. IQV, S.A. and the SELLER offer this product, and the Buyer and User accept it, subject to the foregoing Conditions of Sale and Warranty which may be varied only by agreement in writing signed by a duly authorized representative of IQV, S.A.

20150226 CLL



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**FEE**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP Barcode No.: D426478      File Symbol No.: 35484-A      Decision No.: 490508  
PC Code: 113501      Action Code: R 333  
Food Use: Yes      Product Name: Metalaxyl Technical

Date: March 31, 2015

SUBJECT: Product Chemistry Review of the Manufacturing Use Product, Metalaxyl Technical

FROM: Bruce F. Kitchens, Chemist  
Chemistry, Inert and Toxicology Assessment Branch/RD (7505P)  
Registration Division (7505P)

*Bruce F. Kitchens*  
*31 Mar 2015*

TO: RM #21, Hope Johnson/Marcel Howard  
Fungicide Branch  
Registration Division (7505P)

*SPBm 3/31/15*

INTRODUCTION:

The registrant, Industrias Quimicas del Valles, SA (IQV, SA), is responding to a previous product chemistry review for the proposed manufacturing use product, Metalaxyl Technical (D421173 3/11/15). In that review, it was determined that the data requirements for discussion of the formation of impurities, stability to metals and metal ions and oxidation/reduction were not satisfied. The active ingredient in this product is Metalaxyl at a label nominal concentration of 98.6% a.i. This product is intended for use in the manufacture of fungicide end-use products. With this package, the registrant has submitted responses to the product chemistry questions, product chemistry data contained in MRID# 495890-01 and a data matrix dated 3/18/15. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

CITAB has reviewed this submission and reports the following findings:

1. The discussion of the formation of impurities has been revised (MRID# 495890-01) and now correctly identifies impurity 2. See the confidential appendix for details.
2. The data requirement for (830.6313) stability to normal and elevated temperatures, metals and metal ions has been determined to be not applicable to this product. The product was stable at normal and elevated temperatures. The registrant states in the data matrix dated 3/18/15 that the product is not expected to come into contact with metals and metal ions.
3. The data requirement for (830.6314) oxidation/reduction: chemical incompatibility has been determined to be not applicable to this product. The registrant states in the data matrix dated 3/18/15 that this product does not contain oxidizing or reducing agents. Additionally, the 1994 RED (Reregistration Eligibility Decision) for metalaxyl technical products waives this data requirement.

DP Barcode No.: D426478  
PC Code: 113501  
Food Use: Yes

File Symbol No.: 35484-A  
Action Code: R 333  
Product Name: Metalaxyl Technical

Decision No.: 490508

## CONCLUSIONS:

CITAB has reviewed this submission and concludes the following:

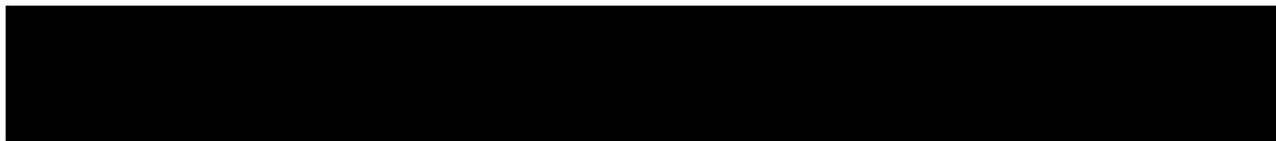
1. The data requirement specified in 40 CFR 158.340 with respect to the discussion of the formation of impurities is satisfied. The registrant has clarified the identity of the impurity in question (Imp 2). See the confidential appendix for details.
2. The data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties for stability to normal and elevated temperatures, metals and metal ions is satisfied. The product is stable to normal and elevated temperatures. The registrant states in the data matrix dated 3/18/15 that the product is not expected to come into contact with metals and metal ions. This portion of the data requirement is not applicable. No additional action is required by the registrant.

The data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties for oxidation/reduction: chemical incompatibility is waived according to the 1994 Metalaxyl RED. No additional action is required by the registrant.

DP Barcode No.: D426478  
PC Code: 113501  
Food Use: Yes

File Symbol No.: 35484-A Division No.: 490508  
Action Code: R 333  
Product Name: Metalaxyl Technical

**CONFIDENTIAL APPENDIX**



\*Manufacturing process information may be entitled to confidential treatment\*

**FEE**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE: 421173  
PC CODE: 113501  
FOOD USE: Yes

FILE SYMBOL No.: 35484-A  
ACTION CODE: R333  
PRODUCT NAME: Metalaxyl Technical

DECISION NO.: 490508

DATE: March 11, 2015

SUBJECT: Product Chemistry Review of the Manufacturing Use Product, Metalaxyl Technical

FROM: Bruce F. Kitchens, Chemist  
Product Chemistry Team  
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

TO: RM # 21, Hope Johnson/Marcel Howard  
Fungicide Branch/RD (7505P)

*Bruce Kitchens*  
*March 11, 2015*  
*SBM 03/11/15*

INTRODUCTION:

The applicant, Industrias Quimicas del Valles, S.A. (IQV, S.A.), submitted an application for approval of the new technical grade product, Metalaxyl Technical. In support of this application, the applicant submitted Group A and Group B product chemistry data with MRID Nos. 493614-01 through 493614-14. The CSF for the basic formulation dated 04/14/2014 was also submitted. CITAB has been asked to determine the acceptability of the product chemistry data and basic CSF.

SUMMARY OF FINDINGS:

1. Group A Guidelines:

830.1550 (Product Identity & Composition)

Active ingredient and process-related impurities are listed on the basic CSF dated 04/14/2014. Their chemical structures are included on Page 15 and Page 16 of the confidential appendix in MRID 493614-02. The nominal concentration of the active ingredient proposed on the basic CSF (98.6%, nominal) is the average derived from the 5-batch preliminary analysis (see Page 13 of the confidential appendix in MRID 493614-02), and matches that on the product label. The CAS # of the active ingredient was not provided on the proposed basic CSF.

830.1600 (Description of Materials Used to Produce the Product)

The submitted data are acceptable (MRID 493614-01). Product specifications for the starting materials were provided.



DP BARCODE: 421173  
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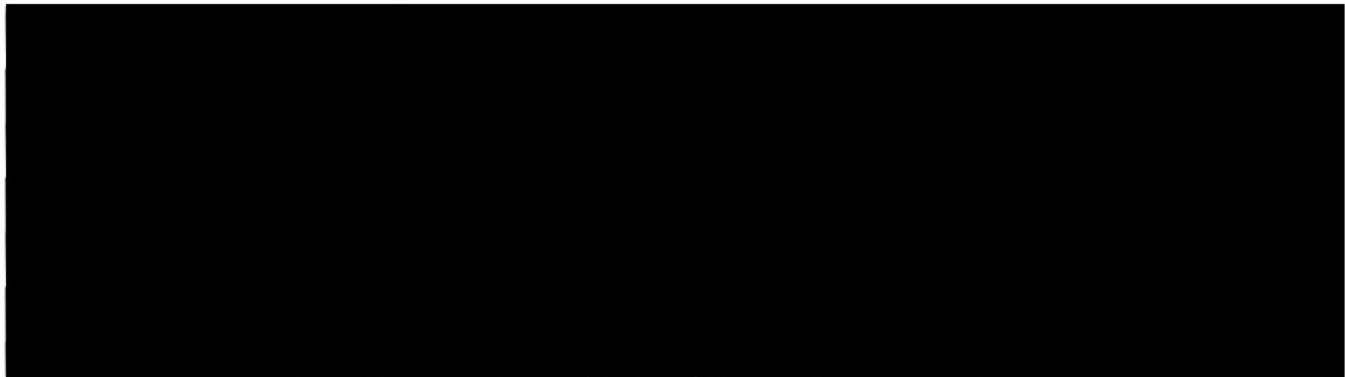
\*Manufacturing process information may be entitled to confidential treatment\*

#### 830.1620 (Description of Production Process)

The submitted data are acceptable (MRID 493614-01).

#### 830.1670 (Discussion of the Formation of Impurities)

The submitted data requires upgrading. Detailed information regarding the origins of impurities was provided (MRIDs 493614-01). Potential impurities were identified and quantified as part of the five-batch analysis (MRIDs 493614-02, 493614-03 and 493614-04). No impurities of potential toxicological concern are present at levels greater than 0.1%.



#### 830.1750 (Certified Limits)

The submitted data are acceptable. The upper and lower certified limits for the A.I., and the upper certified limits for the impurities are within the range of the guideline OCSPP 830.1750 recommendation. The nominal concentrations of the active ingredient and impurities proposed on the basic CSF are the same as the averages derived from the 5-batch preliminary analysis.

#### 830.1800 (Enforcement Analytical Method)



### 2. Group B guidelines (Physical-Chemical Properties):

The registrant submitted experimental data for color, physical state, odor, stability to normal and elevated temperatures, flammability, explosability, pH, UV/visible absorption, melting point, boiling point, density, dissociation constant in water, and partition coefficient (MRIDs 493614-06, 493614-08 through 493614-12). Literature data was cited for water solubility and vapor pressure (MRID 493614-06).

\*Quality control process information may be entitled to confidential treatment\*

DP BARCODE: 421173  
PC CODE: 113501  
FOOD USE: Yes

FILE SYMBOL No.: 35484-A  
ACTION CODE: R333  
PRODUCT NAME: Metalaxyl Technical

DECISION NO.: 490508

The registrant submitted data of two-week accelerated studies (aging at 54 °C for 2 weeks) for these two guidelines: storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320).

The data submitted for oxidation/reduction (guideline 830.6314) is not acceptable (MRID 493614-07). No data was submitted for stability to metals and metal ions, and no explanation was provided. No data was submitted for miscibility, dielectric breakdown voltage, viscosity, and boiling point, on the basis that they were not applicable to or not required for the product (see Data Matrix).

#### CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted to support the proposed basic CSF for Technical TGAi "Metalaxyl Technical" (produced by Industrias Químicas del Valles, S.A. (IQV, S.A.)) and has concluded that:

1. The data submitted for guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis), 830.1750 (certified limits) and guideline 830.1800 (enforcement analytical method) are acceptable.
2. The data for 830.1670 (discussion of the formation of impurities) requires upgrading. The registrant proposed Impurity 2 to be [REDACTED] in MRID 493614-01 which is a [REDACTED]. It is not the same compound as Impurity 2 [REDACTED] that was quantified in MRID 493614-02. The identification of impurity 2 requires clarification.
3. The proposed basic CSF dated 14 Apr 2014 is acceptable. The lower and upper certified limits for the A.I. are within EPA's Standard Certified Limits.
4. Except for the data for stability to metals and metal ions, oxidation/reduction: chemical incompatibility, the data submitted for other 830 series Group B guidelines are acceptable. The registrant is required to submit data for these data requirements.

\*Manufacturing process information may be entitled to confidential treatment\*

DP BARCODE: 421173  
PC CODE: 113501  
FOOD USE: Yes

FILE SYMBOL No.: 35484-A  
ACTION CODE: R333  
PRODUCT NAME: Metalaxyl Technical

DECISION NO.: 490508

830.1550. Product Identity & Composition: (MRID No. 493614-01 and 493614-02)

Common Name: Metalaxyl Technical

Chemical name (CAS): Methyl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-DL-alaninate

(IUPAC): Methyl N-(methoxyacetyl)-N-(2,6-xilyl)-DL-alaninate

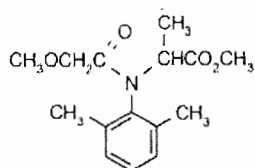
CAS No.: 57837-19-1

PC Code No.: 113501

Empirical Formula:  $C_{15}H_{21}NO_4$

Molecular Weight: 279.3 g/mole

Structural Formula:



METALAXYL

DP Barcode No.: 421173  
 PC Code: 113501  
 Food Use: No

File Symbol No.: 35484-A  
 Action Code: R 333  
 Product Name: Metalaxyl

Decision No.: 490508

Table 1. Manufacturing and Impurity Data for Technical TGA1 "Metalaxyl Technical"

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	493614-01, 493614-02 CSF (dated 04/14/2014)	A	The active ingredient was adequately described.
830.1600	Description of materials used to produce the product	493614-01	A	Specifications of the starting materials were provided.
830.1620	Description of production process	493614-01	A	No quality control measures were provided
830.1670	Discussion of formation of impurities	493614-01, 493614-03, 493614-04	U	The identities and origins of potential impurities were provided. However, the identity of Impurity 2 requires clarification.
830.1700	Preliminary analysis	493614-02	A	Five-batch analysis of the A.I. and impurities was provided.
830.1750	Certified limits	493614-01, CSF (dated 4/14/2014)	A	The lower and upper certified limits for the A.I. are within EPA's Standard Certified Limits.
830.1800	Enforcement analytical method	493614-02	A	The active ingredient and impurities were determined by [REDACTED]
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

\*Manufacturing process information may be entitled to confidential treatment\*

\*Quality control process information may be entitled to confidential treatment\*

DP Barcode No.: D421173  
PC Code: 113501  
Food Use: No

File Symbol No.: 35484-A  
Action Code: R333  
Product Name: Metalaxyl Technical

Decision No.: 490508

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of Technical TGA1 "Metalaxyl Technical"				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	493614-05	A	Colorless
830.6303	Physical state	493614-05	A	Crystalline powder
830.6304	Odor	493614-05	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	493614-06	U	The product is stable at ambient and elevated temperature. No data was submitted for stability to metals and metal ions.
830.6314	Oxidation/reduction: chemical incompatibility	493614-07	N	The data submitted does not meet guideline 830.6314 requirements as the reduction potential was not evaluated. The product should be tested for compatibility with water, monoammonium phosphate or carbon dioxide, powdered zinc or iron, and potassium permanganate.
830.6315	Flammability	493614-08	A	The product is not flammable.
830.6316	Explosibility	493614-09	A	The product is not explosive.
830.6317	Storage stability	493614-06	A	The two-week storage stability study shows the product is stable at ambient and elevated temperature.
830.6319	Miscibility		NA	The product is a solid.
830.6320	Corrosion characteristics	493614-06	A	No significant change was observed from the two-week corrosion characteristics study.
830.7000	pH	493614-06	A	3.85
830.7050	UV/Visible absorption	493614-10	A	Refer to Page 13 of MRID 493614-10 for results.
830.7100	Viscosity		NA	The product is a solid.
830.7200	Melting point	493614-11	A	73 °C
830.7220	Boiling point	493614-09	A	334 ± 0.5 °C (pure A.I.); 339 ± 0.5 °C (technical grade A.I.)
830.7300	Density	493614-11	A	(1.26 ± 0.06) g/mL at 20 °C
830.7370	Dissociation constants in water (DC)	493614-06	NA	The product is not a salt and does not contain acid or base functionality.
830.7550	Partition coefficient	493614-12	A	logP <sub>ow</sub> = 1.96 ± 0.003
830.7840	Water solubility	493614-06	A	8400 ppm at 22 °C (from literature)
830.7950	Vapor pressure	493614-06	A	0.75 mPa at 25 °C (from literature)
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers				



DP Barcode No.: D421173  
PC Code: 113501  
Food Use: No

File Symbol No.: 35484-A  
Action Code: R333  
Product Name: Metalaxyl Technical

Decision No.: 490508

## DATA EVALUATION RECORD

**Metalaxyl**  
(Metalaxyl Technical)

**STUDY TYPES:** Product Identity and Composition (OCSPP 830.1550)  
Description of Materials Used to Produce the Product (OCSPP 830.1600)  
Description of the Formulation Process (OCSPP 830.1650)  
Discussion of Formation of Impurities (OCSPP 830.1670)  
Preliminary Analysis (OCSPP 830.1700)  
Certified Limits (OCSPP 830.1750)  
Enforcement Analytical Method (OCSPP 830.1800)  
Physical and Chemical Characteristics (OCSPP 830.6302-830.7950)

MRIDs 493614-01 through 493614-14

Prepared for  
Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Prepared by  
Summitec Corporation  
9724 Kingston Pike, Suite 602  
Knoxville, Tennessee 37922

Task Order No. 3-A-319

Primary Reviewer:  
Maolian Chen, Ph.D.

Signature: Maolian Chen <sup>AE</sup>  
Date: FEB 24 2015

Secondary Reviewers:  
Eric B. Lewis, M.S.

Signature: Eric B. Lewis  
Date: FEB 24 2015

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross  
Date: FEB 24 2015

Quality Assurance:  
Angie M. Edmonds, B.S.

Signature: Angie M. Edmonds  
Date: FEB 24 2015

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Summitec Corporation for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 35484-A/Metalaxyl Technical MUP  
DP Barcode: 420724  
PC Code: 113501

From: Marianne Lewis, Biologist  
Insecticides/Rodenticides Branch  
Registration Division (7505P)

To: Hope Johnson, PM 21  
Fungicide Branch  
Registration Division (7505P)

Applicant: Industrias Quimicas del Valles  
c/o Landis International, Inc.  
P.O. Box 5126  
Valdosta, GA 31603-5126

*Marianne Lewis*  
*SCR* *6/6/14*

FORMULATION FROM EPA Reg. No. 35484-A LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Metalaxyl: .....	98.6%
<u>Inert Ingredient(s):</u> .....	1.4%
Total	100.0%



BACKGROUND: The registrant is claiming similarity to EPA Reg. No. 42750-242 and doing a 'cite all' to support the registration of their new product, EPA Reg. No. 35484-A. After reviewing the CSF's for the subject product and EPA Reg. No. 35484-A, the EPA will assign the following acute toxicity categories to the subject product: acute oral (81-1) – III; acute dermal (81-2) – IV; acute inhalation (81-3) – IV; primary eye irritation (81-4) – II; primary skin irritation (81-5) – IV; and will be classified as a non sensitizer (81-6).

RECOMMENDATIONS:

- The subject product will be assigned the toxicity categories listed above.
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 35484-A is currently:

Acute Oral	III
Acute Dermal	IV
Acute Inhalation	IV
Primary Eye	II
Primary Dermal	IV
Skin sensitization	non sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.

**LABELING:**

**ID #:** 035484-A                      METALAXYL TECHNICAL MUP

**SIGNAL WORD:**                      **WARNING**                      **AVISO**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Causes substantial but temporary eye injury. Harmful if swallowed. Avoid contact with eyes or clothing. Wear protective eyewear (goggles, face shield, safety glasses), long sleeved shirt and long pants, shoes, and socks.

**FIRST AID:**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**USER SAFETY RECOMMENDATIONS:**

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

**NOTE TO PHYSICIAN:**

Probable mucosal damage may contraindicate the use of gastric lavage.

---

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category II. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

**Tasha Lott**

---

**From:** Johnson, Hope <Johnson.Hope@epa.gov>  
**Sent:** Thursday, March 12, 2015 11:24 AM  
**To:** Crystal Layton  
**Cc:** Howard, Marcel; Giles-Parker, Cynthia  
**Subject:** FW: 35484-A- PC issues and renegotiation need

Good morning,

Per our conversation, the current product chemistry issues are as follows:

- 1) 830.1670 (Discussion of the Formation of Impurities)- identity of Impurity 2 (identified by phone to you) needs clarification between MRID -01 and -02
- 2) 830.6313 (stability to normal and elevated temperatures, metals and metal ions)- No data was submitted regarding stability to metals and metal ions
- 3) 830.6314 (oxidation/reduction)- reduction potential was not evaluated. Product should be tested for compatibility with water, monoammonium phosphate or carbon dioxide, powdered zinc or iron, and potassium permanganate.

Due to the above data issues, a renegotiation of 60 days is needed to allow submission of the outstanding data and review. We will make every effort to review this in a timely fashion once submitted.

Please respond citing the following, and accepting the 60 day renegotiation from March 16, 2015 to May 14, 2015. EPA File Symbol Number 35484-A; Decision Number 490508. If you could send this response today I would appreciate it.

Thank you,

Hope  
Hope A. Johnson  
Product Manager 21  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division  
Fungicide Branch  
Phone: 703-305-5410  
Mail Code 7505P

**From:** Johnson, Hope  
**Sent:** Thursday, March 12, 2015 6:26 AM  
**To:** 'Crystal Layton'  
**Cc:** Howard, Marcel  
**Subject:** 35484-A- please contact me this morning

Good morning,

e-Submission

I am hopeful that Marcel was able to speak with you yesterday regarding this action. Product Chemistry has notified us of deficiencies so we cannot move forward with this application until those are resolved. Therefore, we need to renegotiate this action. Please call me at your earliest convenience today.

Thank you,

Hope A. Johnson  
Product Manager 21  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division  
Fungicide Branch  
Phone: 703-305-5410  
Mail Code 7505P



March 18, 2015

Phone 703-305-5410

FEDERAL EXPRESS

Hope Johnson (PM-21)  
Fungicide Branch  
Registration Division  
U. S. EPA Office of Pesticide Programs - 7505P  
Document Processing Desk  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

SUBJECT: Response to Product Chemistry Deficiencies for EPA file symbol 35484-A

Dear Ms. Johnson,

Landis International, Inc. (hereinafter Landis), Consultant and Regulatory Agent, herein submits on behalf of Industrias Químicas del Vallés, S.A. EPA Company Number 35484, (hereinafter IQV, SA) a response to product chemistry deficiencies noted in the EPA email dated 3/12/2015 for Metalaxyl Technical EPA file symbol 35484-A:

1. 830.1670 (Discussion of the Formation of Impurities) - A revised report is being submitted with this application clarifying impurity 2.
2. 830.6313 (Stability to normal and elevated temperatures, metals and metal ions) - Stability to metals and metal ions is not required as the product is not expected to come into contact with metals or metal ions per 40 CFR 158.310 test note 12. Please see the Data Matrix, EPA form 8570-35 where this information has been noted.
3. 830.6314 (Oxidation/reduction) - This product is not an oxidizer or a reducer. Reduction is not required as this product is not a reducer per 40 CFR 158.310 test note 13. This requirement has been waived for metalaxyl technical products per the September 1994 Reregistration Eligibility Decision Metalaxyl. Please see the Data Matrix, EPA form 8570-35 where this information has been noted.

The study report in this application has been formatted according to PR Notice 2011-3.

The data transmittal document reference all of the documents being submitted and has been created to assist the regulators in determining the location of specific documents.

MRID numbers are as follows:

MRID Nos. 49589000-49589001

Metalaxyl Technical

The data transmittal document contains details of the submission documents to include:  
Document Description, OCSPP Guideline Number, and MRID Number.

The following materials are enclosed in support of this application for registration:

- Cover letter
- Data Transmittal Document
- Two copies of the DVD containing a zip file for Metalaxyl Technical which include:
  - Cover letter
  - Data Transmittal Document
  - EPA Forms (8570-1, 8570-34, and 8570-35)
  - EPA email dated March 12, 2015
  - Data supporting the application for registration [electronic submission of documents using e-DOSSIER].

Please direct any questions regarding this response to:  
Crystal Layton, Landis International, Inc. at 229-247-6472 or via e-mail at  
[clayton@landisintl.com](mailto:clayton@landisintl.com) if you have any questions or concerns.

Sincerely,



Crystal Layton  
Regulatory Product Manager  
Landis International, Inc.  
Regulatory Agent for Industrias Químicas del Vallés, S.A. (IQV, SA)

**DATA TRANSMITTAL DOCUMENT****Submitter:****Industrias Químicas del Vallés, S.A. (IQV, SA)**

Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain)

c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126

Company Contact: \_\_\_\_\_

Typed Name of Signer: Crystal Layton

Phone Number: 229-247-6472

Fax Number: 229-242-1562

Email Address: clayton@landisintl.com

**Regulatory Action in Support of Which this Package is Submitted:**

EPA Registration Number: 35484-A, Metalaxyl Technical

Product Chemistry Deficiencies

**Submission Date:**

03/18/2015

**List of Submitted Documents:**

Description	Guideline Number	MRID
Cover Letter	NA	ADMIN
Data Transmittal Document	NA	49589000
Application for Pesticide Registration EPA Form 8570-1	NA	ADMIN
Certification with Respect to Citation of Data EPA Form 8570-34	NA	ADMIN
Data Matrix (Agency Copy) EPA Form 8570-35	NA	ADMIN
Data Matrix (Public Copy) EPA Form 8570-35	NA	ADMIN
EPA email dated 3/12/2015	NA	ADMIN
Metalaxyl Technical Discussion of Formation of Impurities	830.1670	49589001





**Fee for Service**

{965857}~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

21

Receipt No.

S-

965857

EPA File Symbol/Reg. No.

35484-A

Pin-Punch Date:

3/19/2015



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ \_\_\_\_

Parent/Child Decisions:

☐ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:

*Kimmon*

Date:

*3/23/15*

Remarks:

**e-Submission**

*Resubmission - Deficiency Response*



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Industrias Químicas del Vallés, S.A. (IQV, SA)

Applicant's/Registrant's Name, Address, and Telephone Number Avenida Rafael Casanova 81 08100 Mollet del Vallés  
 c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126 (229)-247-6472

EPA Registration Number/File Symbol  
 35484-A

Active Ingredient(s) and/or representative test compound(s)  
 Metalaxyl

Date  
 03/18/2015

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
 Technical Grade Active Ingredient

Product Name  
 Metalaxyl Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*Crystal Layton*

Date

03/18/2015

Typed or Printed Name and Title

Crystal Layton, Regulatory Agent for IQV, S.A.



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number Industrias Químicas del Vallés, S.A. (IQV, SA)/35484-A	2. EPA Product Manager Hope Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Metalaxyl Technical	PM # 21	
5. Name and Address of Applicant (Include Zip Code) Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126 <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:  EPA. Reg. No. _____ Product Name _____

### Section - II

<input type="checkbox"/> Amendment - Explain Below <input checked="" type="checkbox"/> Resubmission in Response to Agency Letter Dated <u>3/12/2015</u> <input type="checkbox"/> Notification - Explain Below	<input type="checkbox"/> Final Printed Labels in Response to Agency Letter Dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain Below
---	---

**Explanation:** Use additional pages(s) if necessary. (For Section I and Section II.)

This submission is in response to the Agency e-mail dated 3/12/2015 regarding product chemistry deficiencies for EPA file symbol 35484-A.

### Section - III

1. Material This Product Will be Packaged In:			2. Type of Container
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <b>*Certification Must be Submitted</b>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging Weight. Number per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package Weight. Number per Container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>with internal plastic</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 55.11 lbs (25 kg)	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Leaflet Accompanying Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithographed <input type="checkbox"/> Paper Glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Crystal Layton	Title Regulatory Agent for IQV, S.A.	Telephone Number (Include Area Code) 229-247-6472
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Agent for IQV, S.A.	
4. Typed Name Crystal Layton	5. Date 03/18/2015	
<b>e-Submission</b>		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 3/18/2015	EPA Reg No./File Symbol 35484-A	Page 1 of 7
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126	<b>Product:</b> Metalaxyl Technical	

**Ingredient**  
Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Identity and Composition</b>					
830.1550	Product identity and composition	49361401	IQV, SA	OWN	
830.1600	Description of materials used to produce the product	49361401	IQV, SA	OWN	
830.1620	Description of the production process	49361401	IQV, SA	OWN	
830.1650	Description of formulation process	49361401	IQV, SA	OWN	
830.1670	Discussion of formation of impurities	49361401	IQV, SA	OWN	
<b>Analysis and Certified Limits</b>					
830.1700	Preliminary Analysis	49361402 49361403 49361404	IQV, SA	OWN	
830.1750	Certified limits	49361401	IQV, SA	OWN	
830.1800	Enforcement analytical method	49361402 49361403 49361404	IQV, SA	OWN	
<b>Physical and Chemical Characteristics</b>					
830 6302	Color	49361405	IQV, SA	OWN	

<b>Signature</b> 	<b>Name and Title:</b> Crystal Layton, Regulatory Agent for IQV, S.A.	<b>Date</b> 03/18/2015
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e-Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 3/18/2015	EPA Reg No./File Symbol 35484-A	Page 2 of 7
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126	<b>Product:</b> Metalaxyl Technical	

**Ingredient**  
Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical state	49361405	IQV, SA	OWN	
830.6304	Odor	49361405	IQV, SA	OWN	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	49361406	IQV, SA	OWN	See Footnote 1.
830.6314	Oxidation/reduction: chemical incompatibility	49361407	IQV, SA	OWN	See Footnote 2.
830.6315	Flammability	49361408	IQV, SA	OWN	
830.6316	Explosibility	49361409 49361414	IQV, SA	OWN	
830.6317	Storage stability	49361406	IQV, SA	OWN	
830.6319	Miscibility	N/A	N/A	N/A	Test substance is a solid.
830.6320	Corrosion characteristics	49361406	IQV, SA	OWN	
830.6321	Dielectric breakdown voltages	N/A	N/A	N/A	Not required for MP/TGAI
830.7000	pH	49361406	IQV, SA	OWN	
830.7050	UV/visible light absorption	49361410	IQV, SA	OWN	

<b>Signature</b> 	<b>Name and Title:</b> Crystal Layton, Regulatory Agent for IQV, S.A.	<b>Date</b> 03/18/2015
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DATA MATRIX

Date 3/18/2015		EPA Reg No./File Symbol 35484-A		Page 3 of 7	
Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126			Product: Metalaxyl Technical		
Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	N/A	N/A	N/A	Test substance is a solid.
830.7200	Melting point/melting range	49361411	IQV, SA	OWN	
830.7220	Boiling point/boiling range	49361409	IQV, SA	OWN	
830.7300	Density, bulk density or specific gravity	49361411	IQV, SA	OWN	
830.7370	Dissociation constants in water	49361406	IQV, SA	OWN	
830.7520	Particle size, fiber length, and diameter distribution	N/A	N/A	N/A	Test substance is soluble.
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	49361412	IQV, SA	OWN	
830.7840 830.7860	Water solubility	49361406 49361413	IQV, SA	OWN	
830.7950	Vapor pressure	49361406	IQV, SA	OWN	
	Acute Toxicity				
870.1100	Acute Oral	"cite-all"	See list below	PAY	

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 03/18/2015
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Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal	"cite-all"	See list below	PAY	
870.1300	Acute Inhalation	"cite-all"	See list below	PAY	
870.2400	Primary Eye Irritation	"cite-all"	See list below	PAY	
870.2500	Primary Skin Irritation	"cite-all"	See list below	PAY	
870.2600	Skin Sensitization	"cite-all"	See list below	PAY	
	All other guideline requirements are satisfied using the "cite-all" method per 40 CFR §152.95.				

Footnotes:

1. 830.6313- Stability to metals and metal ions is not required as the product is not expected to come into contact with metals or metal ions per 40 CFR 158.310 test note 12.
2. 830.6314-This product is not an oxidizer or a reducer. Reduction is not required as this product is not a reducer per 40 CFR 158.310 test note 13. This requirement has been waived for metalaxyl technical products per the September 1994 Reregistration Eligibility Decision Metalaxyl.

List of companies sent offers of compensation, copies of the offer to pay letters are being submitted with the application for registration:

1. Syngenta Crop Protection, LLC 410 Swing Road Greensboro, NC 27419
2. Bayer Cropscience LP, 2 T.W. Alexander Drive Research Triangle Park, NC 27709
3. Abbott Laboratories Diagnostics Division - Dept. 03A4 100 N. Abbott Park Road, Bldg. CP1 Abbott Park, IL 60064
4. E.I. Du Pont de Nemours and Company (S300/419), Manager, Registration & Regulatory Affairs 1007 Market Street Wilmington, DE 19898
5. Rchm & Haas Co. Attn: James V. Hagan 100 Independence Mall West Philadelphia, PA 19106

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 03/18/2015
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Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

6. Wilbur-Ellis Company 2903 S. Cedar Avenue Fresno, CA 93725
7. BASF Corporation Agricultural Products 26 Davis Drive Research Triangle Park, NC 27709
8. Loveland Products, Inc. P.O. Box 1286 Greeley, CO 80632
9. Enimont America, Inc 1211 Ave of the Americas New York, NY 10036
10. NuFarm Americas, Inc. Agt Division 11901 S. Austin Avenue Alsip, IL 60803
11. Chemtura Corporation 199 Benson Road Middlebury, CT 06749
12. Winfield Solutions, LLC P.O. Box 64589 St. Paul, MN 55164
13. Cerexagri, Inc. 630 Freedom Business Center Suite 402 King of Prussia, PA 19406
14. Howard Fertilizer & Chemical Co., Inc. 8306 S. Orange Avenue Orlando, FL 32862
15. Albaugh Inc. Attn: Morris Gaskins, Registrations Manager P.O. Box 2127 Valdosta, GA 31604
16. Valent U.S.A. Corporation 1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596
17. Wilfarm LLC Attn: Kent Kutnink 5401 N. Oak Trafficway Gladstone, MO 64118
18. The Scotts Company 14111 Scottslawn Road Marysville, OH 43041
19. Mobil Oil Corp Marketing Technical Services Dept. 3225 Gallows Rd. Fairfax, VA 22037
20. Gustafson LLC P.O. Box 660065 Dallas, TX 75266
21. Trace Chemicals LLC 2320 Lakecrest Drive Pekin, IL 61554
22. Easy Gardener Products, Inc. 3022 Franklin Ave. Waco, TX 76710
23. Sipcam Agro USA, Inc. 2525 Meridian Pkwy., Suite 350 Durham, NC 27713
24. Monsanto Company (Acetochlor Registration Partnership) 1300 I Street, N.W., Suite 450 East Washington, DC 20005
25. Agricultural Handler Exposure Task Force P.O. Box 509 Macon, MO 63552
26. Sharda USA LLC P.O. Box 640 Hockessin, DE 19707
27. Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
28. Agricultural Reentry Task Force 1350 I Street, N.W. Washington, DC 20005

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 03/18/2015
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Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

29. NuFarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560
30. Irvita Plant Protection N.V.Pos Cabai Office Park, Unit 13 Curacao
31. Phoenix Environmental Care, LLC P.O. Box 370 Valdosta, GA 31603
32. Metalaxyl Task Force c/o Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
33. Generic Endangered Species Task Force (GESTF) 4110 136th Street, Northwest Gig Harbor, WA 98332
34. Outdoor Residential Exposure Task Force, LLC. 1350 I Street, N.W. Washington DC 20005
35. FIFRA Environmental Model Validation Task Force c/o American Crop Protection Association 1156 Firteenth Street, N.W., Suite 400 Washington, DC 20005
36. Sharda Cropchem Limited Domnic Holm, 29th Road Bandra (West), Mumbai - 400050
37. Ceetox, Inc. 4717 Campus Dr. Kalamazoo, MI 49008
38. Interregional Research Project No. 4 Rutgers University 500 College Road East, Suite 201 W Princeton, NJ 08903
39. FIFRA Endangered Species Task Force, L.L.C. c/o Harold Himmelman (Beveridge & Diamond) 1350 I Street, NW Washington DC 20005
40. Spray Drift Task Force McKenna, Long & Aldridge LLP 1900 K Street, NW Washington, DC 20006
41. Nations Ag II, LLC 4515 Falls of Neuse Rd., Suite 300 Raleigh, NC 27609
42. Nation's Ag, LLC 20 Ambriance Drive Burr Ridge, IL 60527
43. Olympus Seed Treatment Formulator, Inc. 4032 Crockers Lake Blvd., STE 818 Sarasota, FL 34238
44. Metalaxyl EDSP Consortium 1150 Connecticut Ave., STE 1100 Washington, DC 20036
45. LG Life Sciences, LTD. 12208 Quinque Lane Clifton, VA 20124

Most of the data submitters that we sent offers to pay for Metalaxyl were the same as those for Metalaxyl-M (Mefenoxam). The exceptions were as follows:  
An offer to pay was not submitted to the following Metalaxyl-M (Mefenoxam) data submitters listed on the DSL (dated 9/29/14) as these companies have only non-technical registrations. Therefore these companies would not own data that would be used to support IQV's Metalaxyl Technical.  
400 Macdermid Agricultural Solutions, Inc. 1001 G Street, N.W., Suite 500 Washington, DC 20001  
66222 Makhteshim Agan Of North America, Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 03/18/2015
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Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		Product: Metalaxyl Technical		
Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

An offer to pay was not made to the following data submitter since IQV's Metalaxyl Technical is not intended for formulation into residential use products.  
74888 Residential Exposure Joint Venture (REJV) 1667 K Street, NW, Suite 300 Washington, DC 20006

Signature <i>C. Layton</i>	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 03/18/2015
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**LANDIS**  
INTERNATIONAL  
R & D MANAGEMENT

ACTION: New product; MUP (technical)

PRIA CATEGORY: R333

FEE: \$18,893

April 23, 2014

Phone 703-305-5410

**VIA FEDERAL EXPRESS**

Hope Johnson (PM-21) (REGFEE)  
Fungicide Branch  
Registration Division  
U. S. EPA Office of Pesticide Programs - 7505P  
Document Processing Desk  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

**SUBJECT: Application for Registration Containing Active Ingredient Metalaxyl  
(PC Code 113501)**

Metalaxyl Technical

EPA Reg. No. 35484-X

Attention: Hope Johnson, PM-21

Landis International, Inc. (hereinafter Landis), Consultant and Regulatory Agent, herein submits on behalf of Industrias Químicas del Vallés, S.A. EPA Company Number 35484, (hereinafter IQV, SA) an application for registration of the following product containing the active ingredient Metalaxyl (PC Code 113501):

Metalaxyl Technical

EPA Reg. No. 35484-X

This application covers new manufacturing use product (PRIA Category R333). The fee for this application is \$18,893. This application package is intended to register Metalaxyl Technical.

Study reports in this application have been formatted according to PR Notice 2011-3.

The data transmittal document references all documents being submitted and has been created to assist the regulators in determining the location of specific documents.

MRID numbers are as follows:

MRID Nos. 49361400-49361414

Metalaxyl Technical

The data transmittal document contains details of the submission documents including: Document Description, OCSPP Guideline Number, and MRID Number.

The following materials are enclosed in support of this application for registration:

- Cover letter
- Data Transmittal Documents
- Two copies of the DVD containing a zip file for Metalaxyl Technical which include:
  - Cover letter
  - Data Transmittal Document
  - EPA Forms (8570-1, 8570-4, 8570-34, and 8570-35)
  - Offer to Pay for Study Citation Letters
  - Draft Labeling for Metalaxyl Technical
  - Data supporting the application for registration [electronic submission of documents using e-DOSSIER].

Please direct any questions regarding this application to:

Crystal Layton, Landis International, Inc. at 229-247-6472 or via e-mail at [clayton@landisintl.com](mailto:clayton@landisintl.com) if you have any questions or concerns.

Sincerely,



Crystal Layton  
Regulatory Product Manager  
Landis International, Inc.  
Regulatory Agent for Industrias Químicas del Vallés, S.A. (IQV, SA)



# Similarity Clinic Screen Completed

Date: 6/10/14

Jacket #: 35488-A

## Actions Done:

Acute Toxicity Review: COMPLETED → JACKET

Acute Toxicity Language for Label: DONE → REVIEW

Product Chemistry Review: CITING - SEND TO  
TRB FOR REVIEW

## Transfer This Jacket To:

PM 21, HOPE JOHNSON



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Industrias Químicas del Vallés, S.A. (IQV, SA)

Applicant's/Registrant's Name, Address, and Telephone Number c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126 (229)-247-6472	EPA Registration Number/File Symbol 35484-X
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Active Inredient(s) and/or representative test compound(s) Metalaxyl	Date 02/26/2015
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General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Technical Grade Active Ingredient	Product Name Metalaxyl Technical
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**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Crystal Layton</i>	Date 02/26/15	Typed or Printed Name and Title Crystal Layton, Regulatory Agent for IQV, S.A.
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<b>Date</b> 2/26/2015		<b>EPA Reg No./File Symbol</b> 35484-X		Page 1 of 6	
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126			<b>Product:</b> Metalaxyl Technical		
<b>Ingredient</b> Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Note</b>
	<b>Product Identity and Composition</b>				
830.1550	Product identity and composition	49361401	IQV, SA	OWN	
830.1600	Description of materials used to produce the product	49361401	IQV, SA	OWN	
830.1620	Description of the production process	49361401	IQV, SA	OWN	
830.1650	Description of formulation process	49361401	IQV, SA	OWN	
830.1670	Discussion of formation of impurities	49361401	IQV, SA	OWN	
	<b>Analysis and Certified Limits</b>				
830.1700	Preliminary Analysis	49361402 49361403 49361404	IQV, SA	OWN	
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830.1800	Enforcement analytical method	49361402 49361403 49361404	IQV, SA	OWN	
	<b>Physical and Chemical Characteristics</b>				
830.6302	Color	49361405	IQV, SA	OWN	

<b>Signature</b> C. Layton	<b>Name and Title:</b> Crystal Layton, Regulatory Agent for IQV, S.A.	<b>Date</b> 02/26/2015
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Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
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830.6304	Odor	49361405	IQV, SA	OWN	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	49361406	IQV, SA	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	49361407	IQV, SA	OWN	
830.6315	Flammability	49361408	IQV, SA	OWN	
830.6316	Explosibility	49361409 49361414	IQV, SA	OWN	
830.6317	Storage stability	49361406	IQV, SA	OWN	
830.6319	Miscibility	N/A	N/A	N/A	Test substance is a solid.
830.6320	Corrosion characteristics	49361406	IQV, SA	OWN	
830.6321	Dielectric breakdown voltages	N/A	N/A	N/A	Not required for MP/TGAI
830.7000	pH	49361406	IQV, SA	OWN	
830.7050	UV/visible light absorption	49361410	IQV, SA	OWN	

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 02/26/2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	2/26/2015	EPA Reg No./File Symbol	35484-X	Page 3 of 6	
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		<b>Product:</b> Metalaxyl Technical			
<b>Ingredient</b> Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	N/A	N/A	N/A	Test substance is a solid.
830.7200	Melting point/melting range	49361411	IQV, SA	OWN	
830.7220	Boiling point/boiling range	49361409	IQV, SA	OWN	
830.7300	Density, bulk density or specific gravity	49361411	IQV, SA	OWN	
830.7370	Dissociation constants in water	49361406	IQV, SA	OWN	
830.7520	Particle size, fiber length, and diameter distribution	N/A	N/A	N/A	Test substance is soluble.
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	49361412	IQV, SA	OWN	
830.7840 830.7860	Water solubility	49361406 49361413	IQV, SA	OWN	
830.7950	Vapor pressure	49361406	IQV, SA	OWN	
	Acute Toxicity				
870.1100	Acute Oral	"cite-all"	See list below	PAY	

Signature

C. Layton

Name and Title:

Crystal Layton, Regulatory Agent for IQV, S.A.

Date

02/26/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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**DATA MATRIX**

Date 2/26/2015			EPA Reg No./File Symbol 35484-X	Page 4 of 6	
Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126			Product: Metalaxyl Technical		
Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal	"cite-all"	See list below	PAY	
870.1300	Acute Inhalation	"cite-all"	See list below	PAY	
870.2400	Primary Eye Irritation	"cite-all"	See list below	PAY	
870.2500	Primary Skin Irritation	"cite-all"	See list below	PAY	
870.2600	Skin Sensitization	"cite-all"	See list below	PAY	
	All other guideline requirements are satisfied using the "cite-all" method per 40 CFR §152.95.				

List of companies sent offers of compensation, copies of the offer to pay letters are being submitted with the application for registration:

1. Syngenta Crop Protection, LLC 410 Swing Road Greensboro, NC 27419
2. Bayer Cropscience LP, 2 T.W. Alexander Drive Research Triangle Park, NC 27709
3. Abbott Laboratories Diagnostics Division - Dept. 03A4 100 N. Abbott Park Road, Bldg. CP1 Abbott Park, IL 60064
4. E.I. Du Pont de Nemours and Company (S300/419), Manager, Registration & Regulatory Affairs 1007 Market Street Wilmington, DE 19898
5. Rohm & Haas Co. Attn: James V. Hagan 100 Independence Mall West Philadelphia, PA 19106
6. Wilbur-Ellis Company 2903 S. Cedar Avenue Fresno, CA 93725
7. BASF Corporation Agricultural Products 26 Davis Drive Research Triangle Park, NC 27709
8. Loveland Products, Inc. P.O. Box 1286 Greeley, CO 80632
9. Enimont America, Inc 1211 Ave of the Americas New York, NY 10036
10. NuFarm Americas, Inc. Agt Division 11901 S. Austin Avenue Alsip, IL 60803
11. Chemtura Corporation 199 Benson Road Middlebury, CT 06749

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 02/26/2015
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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date	2/26/2015	EPA Reg No./File Symbol	35484-X	Page 5 of 6
Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		Product: Metalaxyl Technical		
Ingredient Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

12. Winfield Solutions, LLC P.O. Box 64589 St. Paul, MN 55164
13. Cerexagri, Inc. 630 Freedom Business Center Suite 402 King of Prussia, PA 19406
14. Howard Fertilizer & Chemical Co., Inc. 8306 S. Orange Avenue Orlando, FL 32862
15. Albaugh Inc. Attn: Morris Gaskins, Registrations Manager P.O. Box 2127 Valdosta, GA 31604
16. Valent U.S.A. Corporation 1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596
17. Wilfarm LLC Attn: Kent Kutnink 5401 N. Oak Trafficway Gladstone, MO 64118
18. The Scotts Company 14111 Scottslawn Road Marysville, OH 43041
19. Mobil Oil Corp Marketing Technical Services Dept. 3225 Gallows Rd. Fairfax, VA 22037
20. Gustafson LLC P.O. Box 660065 Dallas, TX 75266
21. Trace Chemicals LLC 2320 Lakecrest Drive Pekin, IL 61554
22. Easy Gardener Products, Inc. 3022 Franklin Ave. Waco, TX 76710
23. Sipcam Agro USA, Inc. 2525 Meridian Pkwy., Suite 350 Durham, NC 27713
24. Monsanto Company (Acetochlor Registration Partnership) 1300 I Street, N.W., Suite 450 East Washington, DC 20005
25. Agricultural Handler Exposure Task Force P.O. Box 509 Macon, MO 63552
26. Sharda USA LLC P.O. Box 640 Hockessin, DE 19707
27. Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
28. Agricultural Reentry Task Force 1350 I Street, N.W. Washington, DC 20005
29. NuFarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560
30. Irvita Plant Protection N.V. Pos Cabai Office Park, Unit 13 Curacao
31. Phoenix Environmental Care, LLC P.O. Box 370 Valdosta, GA 31603
32. Metalaxyl Task Force c/o Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
33. Generic Endangered Species Task Force (GESTF) 4110 136th Street, Northwest Gig Harbor, WA 98332
34. Outdoor Residential Exposure Task Force, LLC. 1350 I Street, N.W. Washington DC 20005

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 02/26/2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

<b>Date</b> 2/26/2015	<b>EPA Reg No./File Symbol</b> 35484-X	<b>Page</b> 6 of 6			
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126	<b>Product:</b> Metalaxyl Technical				
<b>Ingredient</b> Metalaxyl [EPA has determined that Metalaxyl-M (Mefenoxam) data are also used in support of the registration of this product.]					
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Note</b>

35. FIFRA Environmental Model Validation Task Force c/o American Crop Protection Association 1156 Firtteenth Street, N.W., Suite 400 Washington, DC 20005
36. Sharda Cropchem Limited Domnic Holm, 29th Road Bandra (West), Mumbai – 400050
37. Ceetox, Inc. 4717 Campus Dr. Kalamazoo, MI 49008
38. Interregional Research Project No. 4 Rutgers University 500 College Road East, Suite 201 W Princeton, NJ 08903
39. FIFRA Endangered Species Task Force, L.L.C. c/o Harold Himmelman (Beveridge & Diamond) 1350 I Street, NW Washington DC 20005
40. Spray Drift Task Force Mckenna, Long & Aldridge LLP 1900 K Street, NW Washington, DC 20006
41. Nations Ag II, LLC 4515 Falls of Neuse Rd., Suite 300 Raleigh, NC 27609
42. Nation's Ag, LLC 20 Ambriance Drive Burr Ridge, IL 60527
43. Olympus Seed Treatment Formulator, Inc. 4032 Crockers Lake Blvd., STE 818 Sarasota, FL 34238
44. Metalaxyl EDSP Consortium 1150 Connecticut Ave., STE 1100 Washington, DC 20036
45. LG Life Sciences, LTD. 12208 Quinke Lane Clifton, VA 20124

Most of the data submitters that we sent offers to pay for Metalaxyl were the same as those for Metalaxyl-M (Mefenoxam). The exceptions were as follows:  
An offer to pay was not submitted to the following Metalaxyl-M (Mefenoxam) data submitters listed on the DSL (dated 9/29/14) as these companies have only non-technical registrations. Therefore these companies would not own data that would be used to support IQV's Metalaxyl Technical.  
400 Macdermid Agricultural Solutions, Inc. 1001 G Street, N.W., Suite 500 Washington, DC 20001  
66222 Makhteshim Agan Of North America, Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604  
An offer to pay was not made to the following data submitter since IQV's Metalaxyl Technical is not intended for formulation into residential use products.  
74888 Residential Exposure Joint Venture (REJV) 1667 K Street, NW, Suite 300 Washington, DC 20006

<b>Signature</b> 	<b>Name and Title:</b> Crystal Layton, Regulatory Agent for IQV, S.A.	<b>Date</b> 02/26/2015
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Reg Number: 35484-A

Reg. Type: P .ct Registration - Section 3

Status: Under Review (25-Apr-2014)

Name: Metalaxyl Technical

[<View Registration Details>](#)

## (No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
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## ...Decisions...

Data Requirements

D: Pending; 490508; 35484-A; R333; NEW PROD

75-Day Letters

S: 951261 4/24/2014; New Registration; 35

S: 951261 Reg #: 35484-A

Submission Type: New Registration

Resubmission?: ☐ Yes ☒ No

E-Sub #: 5740

Decision #: 490508; R333; NEW PRODUCT; MUP OR END USE PRODUCT V

Submitter Company: INDUSTRIAS QUIMICAS DEL VALLES, SA. (IQV, SA)

Application Date: 23-Apr-2014

OPP Received Date: 24-Apr-2014

Date Sent to Risk manager: 29-Apr-2014

Studies Included?: ☒ Yes ☐ NoFast Track?: ☒ Yes ☐ NoForm A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Howard, Marcel

Received DT:

Editable Due DT:

Submission Due DT: 16-Mar-2015

Response: 0, 24-Apr-2014

Priority Weight:

Priority Points:

Comments: New MUP / Appl. for registration containing Active Ingredient Metalaxyl.

JUN 25 2014

R 5/24

**Memorandum****E-SUBMISSION**Date: 5/2/14To: PM 21, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

April 28, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

LANDIS INTERNATIONAL, INC.  
INDUSTRIAS QUIMICAS DEL VALLES, SA. (IQV, SA)  
3185 MADISON HIGHWAY  
PO.BOX : 5126  
VALDOSTA, GA 31603-5126

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 24-APR-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

**DATA TRANSMITTAL DOCUMENT****Submitter:****Industrias Químicas del Vallés, S.A. (IQV, SA)**

Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain)

c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126

Company Contact: Crystal Layton

Typed Name of Signer: Crystal Layton

Phone Number: 229-247-6472

Fax Number: 229-2421562

Email Address: clayton@landisintl.com

**Regulatory Action in Support of Which this Package is Submitted:**

EPA Registration Number: 35484-X, Metalaxyl Technical

R333 New product; MUP (technical) with unregistered source of active ingredient

**Submission Date:**

04/23/2014

**List of Submitted Documents:**

Description	Guideline Number	MRID
Cover Letter	NA	ADMIN
Data Transmittal Document	NA	49361400
Application for Pesticide Registration EPA Form 8570-1	NA	ADMIN
Confidential Statement of Formula (CSF) EPA Form 8570-4	NA	ADMIN
Certification with Respect to Citation of Data EPA Form 8570-34	NA	ADMIN
Data Matrix (Agency Copy) EPA Form 8570-35	NA	ADMIN
Data Matrix (Public Copy) EPA Form 8570-35	NA	ADMIN



<b>Description</b>	<b>Guideline Number</b>	<b>MRID</b>
Offer to Pay letters	NA	ADMIN
R333 PRIA receipt	NA	ADMIN
Metalaxyl Technical label	NA	ADMIN
Label Certification Statement	NA	ADMIN
Metalaxyl Technical Product Identity and Composition	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, and 830.1750	49361401
Technical Metalaxyl: Determination of Purity and Impurity Profiles of Five Technical Batches	830.1700 and 830.1800	49361402
N-Nitrosamine Compounds in Technical Metalaxyl	830.1700 and 830.1800	49361403
Investigation of Impurity in Technical Metalaxyl Batches	830.1700 and 830.1800	49361404
Metalaxyl: Report on the Study of Appearance of the Purified Active Substance	830.6302, 830.6303, and 830.6304	49361405
Final Report for: Physical and Chemical Characteristics of Technical Metalaxyl	830.6313, 830.6317, 830.6320, 830.7000, 830.7370, 830.7840, 830.7860 and 830.7950	49361406
Metalaxyl – Oxidising Properties	830.6314	49361407
Flammability Determination of Metalaxyl	830.6315	49361408
Metalaxyl: Determination of Boiling Temperature and Explosive Properties	830.7220 and 830.6316	49361409
Metalaxyl: Determination of Spectra	830.7050	49361410
Melting Point/Melting Range and Relative Density of Test Item Metalaxyl Pure	830.7200 and 830.7300	49361411
Partition Coefficient Determination of Metalaxyl	830.7550, 830.7560 and 830.7570	49361412
Solubility of Metalaxyl in Organic Solvents	830.7840 and 830.7860	49361413
Statement Related to the Explosive Properties of Metalaxyl – Active Substance: Metalaxyl	830.6316	49361414



**LANDIS**  
INTERNATIONAL  
R & D MANAGEMENT

ACTION: New product; MUP (technical)

PRIA CATEGORY: R333

FEE: \$18,893

April 23, 2014

Phone 703-305-5410

**VIA FEDERAL EXPRESS**

Hope Johnson (PM-21) (REGFEE)  
Fungicide Branch  
Registration Division  
U. S. EPA Office of Pesticide Programs - 7505P  
Document Processing Desk  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

**SUBJECT: Application for Registration Containing Active Ingredient Metalaxyl  
(PC Code 113501)**

Metalaxyl Technical

EPA Reg. No. 35484-X

Attention: Hope Johnson, PM-21

Landis International, Inc. (hereinafter Landis), Consultant and Regulatory Agent, herein submits on behalf of Industrias Químicas del Vallés, S.A. EPA Company Number 35484, (hereinafter IQV, SA) an application for registration of the following product containing the active ingredient Metalaxyl (PC Code 113501):

Metalaxyl Technical

EPA Reg. No. 35484-X

This application covers new manufacturing use product (PRIA Category R333). The fee for this application is \$18,893. This application package is intended to register Metalaxyl Technical.

Study reports in this application have been formatted according to PR Notice 2011-3.

The data transmittal document references all documents being submitted and has been created to assist the regulators in determining the location of specific documents.

MRID numbers are as follows:

MRID Nos. 49361400-49361414

Metalaxyl Technical

The data transmittal document contains details of the submission documents including: Document Description, OCSPP Guideline Number, and MRID Number.

The following materials are enclosed in support of this application for registration:

- Cover letter
- Data Transmittal Documents
- Two copies of the DVD containing a zip file for Metalaxyl Technical which include:
  - Cover letter
  - Data Transmittal Document
  - EPA Forms (8570-1, 8570-4, 8570-34, and 8570-35)
  - Offer to Pay for Study Citation Letters
  - Draft Labeling for Metalaxyl Technical
  - Data supporting the application for registration [electronic submission of documents using e-DOSSIER].

Please direct any questions regarding this application to:

Crystal Layton, Landis International, Inc. at 229-247-6472 or via e-mail at [clayton@landisintl.com](mailto:clayton@landisintl.com) if you have any questions or concerns.

Sincerely,



Crystal Layton  
Regulatory Product Manager  
Landis International, Inc.  
Regulatory Agent for Industrias Químicas del Vallés, S.A. (IQV, SA)



# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 4-24-14 September 2012

Experts In-Processing Signature: B.B. Date 4-29-14 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>35484-A</u>		EPA Receipt Date: <u>4-24-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)		yes	no		
	<del>*** No inerts to review</del>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)		yes	no		
	b) Cite-All (Fee category experts use)		X			
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with <u>PR Notice 86-5</u>			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application : : : : :			

Comments:

- \* Submitted studies PASSED PRN 11-3 review
- \* Certification w/ respect to Citation of data form was pulled out incorrectly
- \* Contacted submitter on 05/13/2014
- \* Corrections were received on 05/13/2014
- \* Technical & impurities only, no merits to review
- \* Jacket PASSED

LC

MRID: 493014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 29, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-490508  
EPA File Symbol or Registration Number: 35484-A  
Product Name: Metalaxyl Technical  
EPA Receipt Date: 24-Apr-2014  
EPA Company Number: 35484  
Company Name: INDUSTRIAS QUIMICAS DEL VALLES, SA. (IQV, SA)

CRYSTAL LAYTON  
LANDIS INTERNATIONAL, INC.  
INDUSTRIAS QUIMICAS DEL VALLES, SA. (IQV, SA)  
3185 MADISON HIGHWAY, PO Box 5126  
VALDOSTA, GA 31603-5126

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. jh.", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

{951261Ä~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

21

Receipt No.

S-

951261

EPA File Symbol/Reg. No.

35484-A

Pin-Punch Date:

4/24/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R333

Granted:

R333

Amount Due: \$ 18,893.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

*[Signature]*

Date:

4/28/14

Remarks:

Sim Clinic needed - Citing tox + Chem

E-SUBMISSION

**Online Payment****Step 3: Confirm Payment****1 | 2 | 3****Thank you.****Your transaction has been successfully completed.****Pay.gov Tracking Information****Application Name:** PRIA Service Fees**Pay.gov Tracking ID:** 25FDPRLK**Agency Tracking ID:** 74605981365**Transaction Date and Time:** 04/23/2014 11:56 EDT**Payment Summary****Address Information****Account Holder Name:** Crystal Layton**Billing Address:** PO Box 5126**Billing Address 2:****City:** Valdosta**State / Province:** GA**Zip / Postal Code:** 31603-5126**Country:** USA**Account Information****Card Type:** American Express**Card Number:** \*\*\*\*\*1230**Decision Number:****Registration Number:** 35484-X**Company Name:** IQV, SA**Company Number:** 35484**Action Code:** R333**Payment Information****Payment Amount:** \$18,893.00**Transaction Date and Time:** 04/23/2014 11:56 EDT**SUBMISSION**





ACTION: New product; MUP (technical)

PRIA CATEGORY: R333

FEE: \$18,893

April 23, 2014

Phone 703-305-5410

**VIA FEDERAL EXPRESS**

Hope Johnson (PM-21) (REGFEE)  
Fungicide Branch  
Registration Division  
U. S. EPA Office of Pesticide Programs - 7505P  
Document Processing Desk  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

**SUBJECT: Application for Registration Containing Active Ingredient Metalaxyl  
(PC Code 113501)**

Metalaxyl Technical

EPA Reg. No. 35484-X

Attention: Hope Johnson, PM-21

Landis International, Inc. (hereinafter Landis), Consultant and Regulatory Agent, herein submits on behalf of Industrias Químicas del Vallés, S.A. EPA Company Number 35484, (hereinafter IQV, SA) an application for registration of the following product containing the active ingredient Metalaxyl (PC Code 113501):

Metalaxyl Technical

EPA Reg. No. 35484-X

This application covers new manufacturing use product (PRIA Category R333). The fee for this application is \$18,893. This application package is intended to register Metalaxyl Technical

Study reports in this application have been formatted according to PR Notice 2011-3.

The data transmittal document references all documents being submitted and has been created to assist the regulators in determining the location of specific documents.

MRID numbers are as follows:

MRID Nos. 49361400-49361414

Metalaxyl Technical

Page 1 of 2

The data transmittal document contains details of the submission documents including: Document Description, OCSPP Guideline Number, and MRID Number.

The following materials are enclosed in support of this application for registration:

- Cover letter
- Data Transmittal Documents
- Two copies of the DVD containing a zip file for Metalaxyl Technical which include:
  - Cover letter
  - Data Transmittal Document
  - EPA Forms (8570-1, 8570-4, 8570-34, and 8570-35)
  - Offer to Pay for Study Citation Letters
  - Draft Labeling for Metalaxyl Technical
  - Data supporting the application for registration [electronic submission of documents using e-DOSSIER].

Please direct any questions regarding this application to:

Crystal Layton, Landis International, Inc. at 229-247-6472 or via e-mail at [clayton@landisintl.com](mailto:clayton@landisintl.com) if you have any questions or concerns.

Sincerely,



Crystal Layton  
Regulatory Product Manager  
Landis International, Inc.  
Regulatory Agent for Industrias Químicas del Vallés, S.A. (IQV, SA)

**DATA TRANSMITTAL DOCUMENT****Submitter:****Industrias Químicas del Vallés, S.A. (IQV, SA)**

Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain)

c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126

Company Contact: C. Layton

Typed Name of Signer: Crystal Layton

Phone Number: 229-247-6472

Fax Number: 229-2421562

Email Address: clayton@landisintl.com

**Regulatory Action in Support of Which this Package is Submitted:**

EPA Registration Number: 35484-X, Metalaxyl Technical

R333 New product; MUP (technical) with unregistered source of active ingredient

**Submission Date:**

04/23/2014

**List of Submitted Documents:**

Description	Guideline Number	MRID
Cover Letter	NA	ADMIN
Data Transmittal Document	NA	49361400
Application for Pesticide Registration EPA Form 8570-1	NA	ADMIN
Confidential Statement of Formula (CSF) EPA Form 8570-4	NA	ADMIN
Certification with Respect to Citation of Data EPA Form 8570-34	NA	ADMIN
Data Matrix (Agency Copy) EPA Form 8570-35	NA	ADMIN
Data Matrix (Public Copy) EPA Form 8570-35	NA	ADMIN

<b>Description</b>	<b>Guideline Number</b>	<b>MRID</b>
Offer to Pay letters	NA	ADMIN
R333 PRIA receipt	NA	ADMIN
Metalaxyl Technical label	NA	ADMIN
Label Certification Statement	NA	ADMIN
Metalaxyl Technical Product Identity and Composition	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, and 830.1750	49361401
Technical Metalaxyl: Determination of Purity and Impurity Profiles of Five Technical Batches	830.1700 and 830.1800	49361402
N-Nitrosamine Compounds in Technical Metalaxyl	830.1700 and 830.1800	49361403
Investigation of Impurity in Technical Metalaxyl Batches	830.1700 and 830.1800	49361404
Metalaxyl: Report on the Study of Appearance of the Purified Active Substance	830.6302, 830.6303, and 830.6304	49361405
Final Report for: Physical and Chemical Characteristics of Technical Metalaxyl	830.6313, 830.6317, 830.6320, 830.7000, 830.7370, 830.7840, 830.7860 and 830.7950	49361406
Metalaxyl – Oxidising Properties	830.6314	49361407
Flammability Determination of Metalaxyl	830.6315	49361408
Metalaxyl: Determination of Boiling Temperature and Explosive Properties	830.7220 and 830.6316	49361409
Metalaxyl: Determination of Spectra	830.7050	49361410
Melting Point/Melting Range and Relative Density of Test Item Metalaxyl Pure	830.7200 and 830.7300	49361411
Partition Coefficient Determination of Metalaxyl	830.7550, 830.7560 and 830.7570	49361412
Solubility of Metalaxyl in Organic Solvents	830.7840 and 830.7860	49361413
Statement Related to the Explosive Properties of Metalaxyl – Active Substance: Metalaxyl	830.6316	49361414

## Lewis, Marianne

---

**From:** Crystal Layton <clayton@landisintl.com>  
**Sent:** Monday, May 19, 2014 11:17 AM  
**To:** Lewis, Marianne  
**Subject:** RE: EPA Reg. No. 35484-A/Metalaxyl Technical

Dear Marianne,

The Metalaxyl Technical is substantially similar to EPA Reg. No. 42750-242. Please let me know if you need anything additional.

Thank you,

Crystal

Crystal Layton  
Regulatory Product Manager  
Landis International, Inc.  
3185 Madison Highway  
Valdosta, GA 31601 USA  
Phone: (229) 247-6472 Cell: (229) 548-2806  
Fax: (229) 242-1562  
skype: crystal.layton  
email: [clayton@landisintl.com](mailto:clayton@landisintl.com)

**From:** Lewis, Marianne [mailto:Lewis.Marianne@epa.gov]  
**Sent:** Friday, May 16, 2014 2:13 PM  
**To:** Crystal Layton  
**Subject:** EPA Reg. No. 35484-A/Metalaxyl Technical

Ms. Layton,

I am reviewing your new product application package for the Metalaxyl Technical and there are no references to the required acute toxicity studies to support this new technical. Please resubmit your data matrix to me with the acute toxicity studies that you will be citing for this product or cite a product that you think your new product is substantially similar to.

Please return it to me by 5/21/14.

If you have any questions let me know

Marianne

Marianne Lewis  
Biologist  
IRB/RD  
703 308-8043

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 5-15-14

**Jacket #** 35484-A  
**MRID#** 493614

**Content Screen:** Recommend to Pass/Fail

**11-3 Review:** Pass/Fail/NA

**Overall Status:** Recommend to Pass/Fail

**Transfer This Jacket to:**

STEPHEN SCOTTA BLE



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number <small>Industrias Químicas del Vallés, S.A. (IQV, SA)</small> Avenida Rafael Casanova 81 08100 Mollet del Vallés c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126 (229)-247-6472		EPA Registration Number/File Symbol 35484-X
Active Ingredient(s) and/or representative test compound(s) Metalaxyl	Date 4/23/2014	
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Technical Grade Active Ingredient	Product Name Metalaxyl Technical	

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.**

Signature *Crystal Layton*

Date  
05/13/14

Typed or Printed Name and Title  
Crystal Layton, Regulatory Agent for IQV, S.A.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

<b>Date</b> April 23, 2014		<b>EPA Reg No./File Symbol</b> 35484-X		Page 1 of 6	
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		<b>Product:</b> Metalaxyl Technical			
<b>Ingredient</b> Metalaxyl					
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Note</b>
	<b>Product Identity and Composition</b>				
830.1550	Product identity and composition	49361401	IQV, SA	OWN	
830.1600	Description of materials used to produce the product	49361401	IQV, SA	OWN	
830.1620	Description of the production process	49361401	IQV, SA	OWN	
830.1650	Description of formulation process	49361401	IQV, SA	OWN	
830.1670	Discussion of formation of impurities	49361401	IQV, SA	OWN	
	<b>Analysis and Certified Limits</b>				
830.1700	Preliminary Analysis	49361402 49361403 49361404	IQV, SA	OWN	
830.1750	Certified limits	49361401	IQV, SA	OWN	
830.1800	Enforcement analytical method	49361402 49361403 49361404	IQV, SA	OWN	
	<b>Physical and Chemical Characteristics</b>				
830.6302	Color	49361405	IQV, SA	OWN	

<b>Signature</b> C. Layton	<b>Name and Title:</b> Crystal Layton, Regulatory Agent for IQV, S.A.	<b>Date</b> 4/23/14
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DATA MATRIX

Date April 23, 2014	EPA Reg No./File Symbol 35484-X	Page 2 of 6
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126	<b>Product:</b> Metalaxyl Technical	

**Ingredient**

Metalaxyl

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical state	49361405	IQV, SA	OWN	
830.6304	Odor	49361405	IQV, SA	OWN	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	49361406	IQV, SA	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	49361407	IQV, SA	OWN	
830.6315	Flammability	49361408	IQV, SA	OWN	
830.6316	Explosibility	49361409 49361414	IQV, SA	OWN	
830.6317	Storage stability	49361406	IQV, SA	OWN	
830.6319	Miscibility	N/A	N/A	N/A	Test substance is a solid.
830.6320	Corrosion characteristics	49361406	IQV, SA	OWN	
830.6321	Dielectric breakdown voltages	N/A	N/A	N/A	Not required for MP/TGAI
830.7000	pH	49361406	IQV, SA	OWN	
830.7050	UV/visible light absorption	49361410	IQV, SA	OWN	

Signature

C. Layton

Name and Title:

Crystal Layton, Regulatory Agent for IQV, S.A.

Date

4/23/14



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WASHINGTON, D.C. 20460

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DATA MATRIX

<b>Date</b> April 23, 2014			<b>EPA Reg No./File Symbol</b> 35484-X		Page 3 of 6
<b>Applicant's/Registrant's Name &amp; Address</b> Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126			<b>Product:</b> Metalaxyl Technical		
<b>Ingredient</b> Metalaxyl					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	N/A	N/A	N/A	Test substance is a solid.
830.7200	Melting point/melting range	49361411	IQV, SA	OWN	
830.7220	Boiling point/boiling range	49361409	IQV, SA	OWN	
830.7300	Density, bulk density or specific gravity	49361411	IQV, SA	OWN	
830.7370	Dissociation constants in water	49361406	IQV, SA	OWN	
830.7520	Particle size, fiber length, and diameter distribution	N/A	N/A	N/A	Test substance is soluble.
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	49361412	IQV, SA	OWN	
830.7840 830.7860	Water solubility	49361406 49361413	IQV, SA	OWN	
830.7950	Vapor pressure	49361406	IQV, SA	OWN	

<b>Signature</b> 	<b>Name and Title:</b> Crystal Layton, Regulatory Agent for IQV, S.A.	<b>Date</b> 4/23/14
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DATA MATRIX

Date April 23, 2014		EPA Reg No./File Symbol 35484-X	Page 4 of 6		
Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		Product: Metalaxyl Technical			
Ingredient Metalaxyl					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	All other guideline requirements are satisfied using the "cite-all" method per 40 CFR §152.95.				

List of companies sent offers of compensation, copies of the offer to pay letters are being submitted with the application for registration:

1. Syngenta Crop Protection, LLC 410 Swing Road Greensboro, NC 27419
2. Bayer Cropscience LP, 2 T.W. Alexander Drive Research Triangle Park, NC 27709
3. Abbott Laboratories Diagnostics Division - Dept. 03A4 100 N. Abbott Park Road, Bldg. CP1 Abbott Park, IL 60064
4. E.I. Du Pont de Nemours and Company (S300/419), Manager, Registration & Regulatory Affairs 1007 Market Street Wilmington, DE 19898
5. Rohm & Haas Co. Attn: James V. Hagan 100 Independence Mall West Philadelphia, PA 19106
6. Wilbur-Ellis Company 2903 S. Cedar Avenue Fresno, CA 93725
7. BASF Corporation Agricultural Products 26 Davis Drive Research Triangle Park, NC 27709
8. Loveland Products, Inc. P.O. Box 1286 Greeley, CO 80632
9. Enimont America, Inc 1211 Ave of the Americas New York, NY 10036
10. NuFarm Americas, Inc. Agt Division 11901 S. Austin Avenue Alsip, IL 60803
11. Chemtura Corporation 199 Benson Road Middlebury, CT 06749
12. Winfield Solutions, LLC P.O. Box 64589 St. Paul, MN 55164
13. Cerexagri, Inc. 630 Freedom Business Center Suite 402 King of Prussia, PA 19406
14. Howard Fertilizer & Chemical Co., Inc. 8306 S. Orange Avenue Orlando, FL 32862
15. Albaugh Inc. Attn: Morris Gaskins, Registrations Manager P.O. Box 2127 Valdosta, GA 31604
16. Valent U.S.A. Corporation 1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596
17. Wilfarm LLC Attn: Kent Kutnink 5401 N. Oak Trafficway Gladstone, MO 64118
18. The Scotts Company 14111 Scottslawn Road Marysville, OH 43041
19. Mobil Oil Corp Marketing Technical Services Dept. 3225 Gallows Rd. Fairfax, VA 22037

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 4/23/14
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WASHINGTON, D.C. 20460

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DATA MATRIX

Date	April 23, 2014	EPA Reg No./File Symbol	35484-X	Page 5 of 6
Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		Product: Metalaxyl Technical		
Ingredient Metalaxyl				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

20. Gustafson LLC P.O. Box 660065 Dallas, TX 75266
21. Trace Chemicals LLC 2320 Lakecrest Drive Pekin, IL 61554
22. Easy Gardener Products, Inc. 3022 Franklin Ave. Waco, TX 76710
23. Sipcam Agro USA, Inc. 2525 Meridian Pkwy., Suite 350 Durham, NC 27713
24. Monsanto Company (Acetochlor Registration Partnership) 1300 I Street, N.W., Suite 450 East Washington, DC 20005
25. Agricultural Handler Exposure Task Force P.O. Box 509 Macon, MO 63552
26. Sharda USA LLC P.O. Box 640 Hockessin, DE 19707
27. Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
28. Agricultural Reentry Task Force 1350 I Street, N.W. Washington, DC 20005
29. NuFarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560
30. Irvita Plant Protection N.V.Pos Cabai Office Park, Unit 13 Curacao
31. Phoenix Environmental Care, LLC P.O. Box 370 Valdosta, GA 31603
32. Metalaxyl Task Force c/o Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
33. Generic Endangered Species Task Force (GESTF) 4110 136th Street, Northwest Gig Harbor, WA 98332
34. Outdoor Residential Exposure Task Force, LLC. 1350 I Street, N.W. Washington DC 20005
35. FIFRA Environmental Model Validation Task Force c/o American Crop Protection Association 1156 Firteenth Street, N.W., Suite 400 Washington, DC 20005
36. Sharda Cropchem Limited Domnic Holm, 29th Road Bandra (West), Mumbai - 400050
37. Ceetox, Inc. 4717 Campus Dr. Kalamazoo, MI 49008
38. Interregional Research Project No. 4 Rutgers University 500 College Road East, Suite 201 W Princeton, NJ 08903
39. FIFRA Endangered Species Task Force, L.L.C. c/o Harold Himmelman (Beveridge & Diamond) 1350 I Street, NW Washington DC 20005
40. Spray Drift Task Force McKenna, Long & Aldridge LLP 1900 K Street, NW Washington, DC 20006
41. Nations Ag II, LLC 4515 Falls of Neuse Rd., Suite 300 Raleigh, NC 27609
42. Nation's Ag, LLC 20 Ambriance Drive Burr Ridge, IL 60527

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 4/23/14
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401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date April 23, 2014		EPA Reg No./File Symbol 35484-X	Page 6 of 6	
Applicant's/Registrant's Name & Address Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126		Product: Metalaxyl Technical		
Ingredient Metalaxyl				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

43. Olympus Seed Treatment Formulator, Inc. 4032 Crockers Lake Blvd., STE 818 Sarasota, FL 34238

44. Metalaxyl EDSP Consortium 1150 Connecticut Ave., STE 1100 Washington, DC 20036

45. LG Life Sciences, LTD. 12208 Quinque Lane Clifton, VA 20124

Signature 	Name and Title: Crystal Layton, Regulatory Agent for IQV, S.A.	Date 4/23/14
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United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number Industrias Químicas del Vallés, S.A. (IQV, SA)/35484-X	2. EPA Product Manager Hope Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Metalaxyl Technical	PM # 21	
5. Name and Address of Applicant (Include Zip Code) Industrias Químicas del Vallés, S.A. (IQV, SA) Avenida Rafael Casanova 81 08100 Mollet del Vallès (Barcelona-Spain) c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126 <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:  EPA. Reg. No. _____ Product Name _____

### Section - II

<input type="checkbox"/> Amendment - Explain Below <input type="checkbox"/> Resubmission in Response to Agency Letter Dated _____ <input type="checkbox"/> Notification - Explain Below	<input type="checkbox"/> Final Printed Labels in Response to Agency Letter Dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain Below
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**Explanation:** Use additional pages(s) if necessary. (For Section I and Section II.)

This application covers new manufacturing use product (PRIA Category R333). The fee for this application is \$18,893. This application package is intended to register Metalaxyl Technical.

### Section - III

1. Material This Product Will be Packaged In:			2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging Weight.	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package Weight.	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) with internal plastic	
*Certification Must be Submitted				
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 55.11 lbs (25 kg)	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Leaflet Accompanying Label		
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithographed <input type="checkbox"/> Paper Glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other				

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Crystal Layton		Title Regulatory Agent for IQV, S.A.	
		Telephone Number (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Agent for IQV, S.A.	
4. Typed Name Crystal Layton		5. Date 4/23/2014	

